

INSTAND EQA Schemes - from Proficiency Testing to Standardisation

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EURAMET Workshop on Measurement Challenges:
SARS-CoV-2 & Future Pandemics
04 November 2021

Disclosure

Heinz Zeichhardt is
share-holder of

GBD Gesellschaft für Biotechnologische Diagnostik mbH, Berlin

and

share-holder and CEO of

IQVD GmbH - Institut für Qualitätssicherung in der Virusdiagnostik, Berlin

Outlook

- INSTAND External Quality Assessment (EQA) Schemes
- (MK) EQAS for SARS-CoV-2 genome detection (starting April 2020)
 - strong variation of ct-values
 - how to interpret ct-values as positive for SARS-CoV-2

=> standardization of SARS-CoV-2 genome detection needed
- (MK) Use of quantitative comparison samples (CS) for anchoring ct-values
 - for individual labs
 - for defined tests
 - for each individual gene region
- (MK) Results of RNA Harmonization Study (CSWG)
 - good correlation between copies/ml of investigated reference materials and IU/ml of WHO IS (NIBSC 20/146)
- (HZ) EQAS for SARS-CoV-2 antibody detection (starting May 2020)
 - good specificity
 - individual immune responses in regard to target antigens (S/NCP)
 - quantitative results in BAU/ml (WHO IS, NIBSC 20/136)
of different tests in good agreement

EQA Network

Scientific umbrella

German Association for Prevention of Virus Diseases (DVV e.V.)

Society of Virology (GfV e.V.)

German Society for Hygiene and Microbiology (DGHM e.V.)

Partners

Berlin

Teams of

GBD Gesellschaft für Biotechnologische Diagnostik mbH, Berlin

Hans-Peter Grunert

Wolfgang Güthoff

Ulf Dühring

and

IQVD GmbH

Institut für Qualitätssicherung in der Virusdiagnostik, Berlin

and

Düsseldorf

INSTAND-Team

and

38 INSTAND Expert Laboratories

incl.

Robert Koch-Institut

Paul-Ehrlich-Institut

National Reference and Consiliary Labs

and



JRC – Joint Research Centre (BE)

LGC – National Measurement Laboratory (UK)

NIB – National Institute of Biology (SI)

PTB - Physikalisch-Technische Bundesanstalt (DE)

and

NIST - National Institute of Standards and Technology (USA)

INSTAND e.V.

Immunohaematology
(41)

Autoimmune diseases (57)

Haemostasis
(54)

Haematology
(54)

Clinical chemistry
(43)

Trace elements
(50)

Pharmaceuticals and drugs
(152)

> 350

Programs

Virtual EQA schemes
(3)

Virology
(82)

Bacteriology / serology
(47)

Bacterial genome detection
(19)

Parasitology
(8)

Mycology
(7)

Molecular diagnostics
(90)

POCT
(34)

EQAS in virus diagnostics – 2021:

- > 2450 participating laboratories
- from approx. **70** countries worldwide

INSTAND EQA Schemes – 7 Schemes for SARS-CoV-2 Diagnostics

	2020	2021
(340) Virus genome detection - SARS-CoV-2	Apr	
(340) Virus genome detection - coronaviren incl. differentiation SARS-CoV-2 / MERS / different HCoVs	Jun + Nov	Jun + Nov
(409) Virus genome detection - SARS-CoV-2		Mar + Jun + Sep + Nov
(417) Virus genome detection - SARS-CoV-2 VOC Analysis by point mutation analysis and sequencing		Mar + Apr + Jun + Sep + Nov
(431 und 432) Virus genome detection – respiratory virus panel 1 and panel 2 for multiplex tests incl. SARS-CoV-2	Jun + Nov	Jun + Nov
(410) Antigen detection - SARS-CoV-2 for rapid tests and automated immuno assays		Mar + Jun + Sep + Nov
(416) Detection of anti-SARS-CoV-2 (total, IgG, avidity, IgA and IgM)	Jun + Sep + Nov	Mar + Jun + Sep + Nov
(7340) Cooperation – reference materials RKI – Charité Consultant Lab CoV and INSTAND e.V. Quantitative comparison samples (QS) für SARS-CoV-2 QS 1 – 10E7 copies/ml, QS 2 – 10E6 copies/ml	3 Nov + 17 Nov	15 Jan + 17 Feb + ...

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 - individual immune responses in regard to target antigens (S/NCP)
 - quantitative results in BAU/ml (WHO IS, NIBSC 20/136) of different tests in good agreement

INSTAND Expert laboratories for the INSTAND EQA scheme (340) Virus Genome Detection - Coronaviruses incl. SARS-CoV-2

<p>Nationales Konsiliarlaboratorium f. Coronaviren, Charité - Universitätsmedizin Berlin, Institut für Virologie, Campus Charité Mitte Christian Drosten, Victor M. Corman, Daniela Niemeyer</p> 	<p>Medizinische Hochschule Hannover, Institut für Virologie Thomas Schulz, Albert Heim, Wolfram Puppe, Corinna Schmitt</p>	<p>Medizinisches Infektiozentrum Berlin (MIB) Martin Obermeier, Robert Ehret</p>
<p>Philipps Universität Marburg, Institut für Virologie Stephan Becker, Christian Keller, Markus Eickmann</p>	<p>Robert Koch-Institut, Berlin, Abt. Infektionskrankheiten Ralf Dürrwald, Barbara Biere, Janine Reiche</p>	<p>Robert Koch-Institut, Berlin, ZBS 1, Zentrum für Biologische Gefahren und Spezielle Pathogene/ Hochpathogene Viren Andreas Nitsche, Janine Michel</p>
<p>Uniklinik Köln, Institut für Virologie Florian Klein, Rolf Kaiser, Eva Heger, Elena Knops</p>	<p>Universitätsklinikum Bonn, Institut für Virologie Hendrik Streeck, Anna-Maria Eis-Hübinger</p>	<p>Universitätsklinikum Düsseldorf, Institut für Virologie Jörg Timm, Ortwin Adams, Nadine Lübke</p>
<p>Universitätsklinikum Frankfurt, Institut für Medizinische Virologie Sandra Ciesek, Holger F. Rabenau, Annemarie Berger</p>	<p>Universitätsklinikum Freiburg, Institut für Virologie Hartmut Hengel, Daniela Huzly, Marcus Panning, Martin Schwemmler</p>	

National Metrology Institutes

<p>National Measurement Institute LGC, Teddington, Middlesex (UK) Jim Huggett, Denise O'Sullivan and University of Surrey, Guildford, Surrey (UK) Jim Huggett</p> 	<p>Physikalisch-Technische Bundesanstalt, Berlin Rainer Macdonald, Andreas Kummrow, Annabell Plauth, Samreen Falak</p> 	<p>NIST - National Institute of Standards and Technology (USA) Peter M. Valone, Megan Cleveland</p> 
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INSTAND EQA Schemes - Virus Genome Detection

(340) CoV incl. SARS-CoV-2**(409) SARS-CoV-2**

Overview EQA schemes performed 2020			
EQAS prog / term	panel members	number of laboratories having reported results	number of countries
(340) April 2020	7	463	36
(340) June/July 2020	9	635	39
(340) November 2020	7	571	35
(409) March 2021	5	415	26
(340) June 2021	6	392	33
(409) June 2021	4	455	26
(409) September 2021	4	385	27
total:	42	1270	48

for CoV positive panel members:

cell culture supernatants

- SARS-CoV-2 (full virus, heat inactivated)
- MERS CoV (full virus, heat inactivated)
- Human coronaviruses (HCoV)s: E229, NL63, OC43

for CoV negative panel members:

cell culture lysates (MRC-5 cells)

Extra INSTAND EQA Scheme (340) - April 2020

Virus Genome Detection SARS-CoV-2

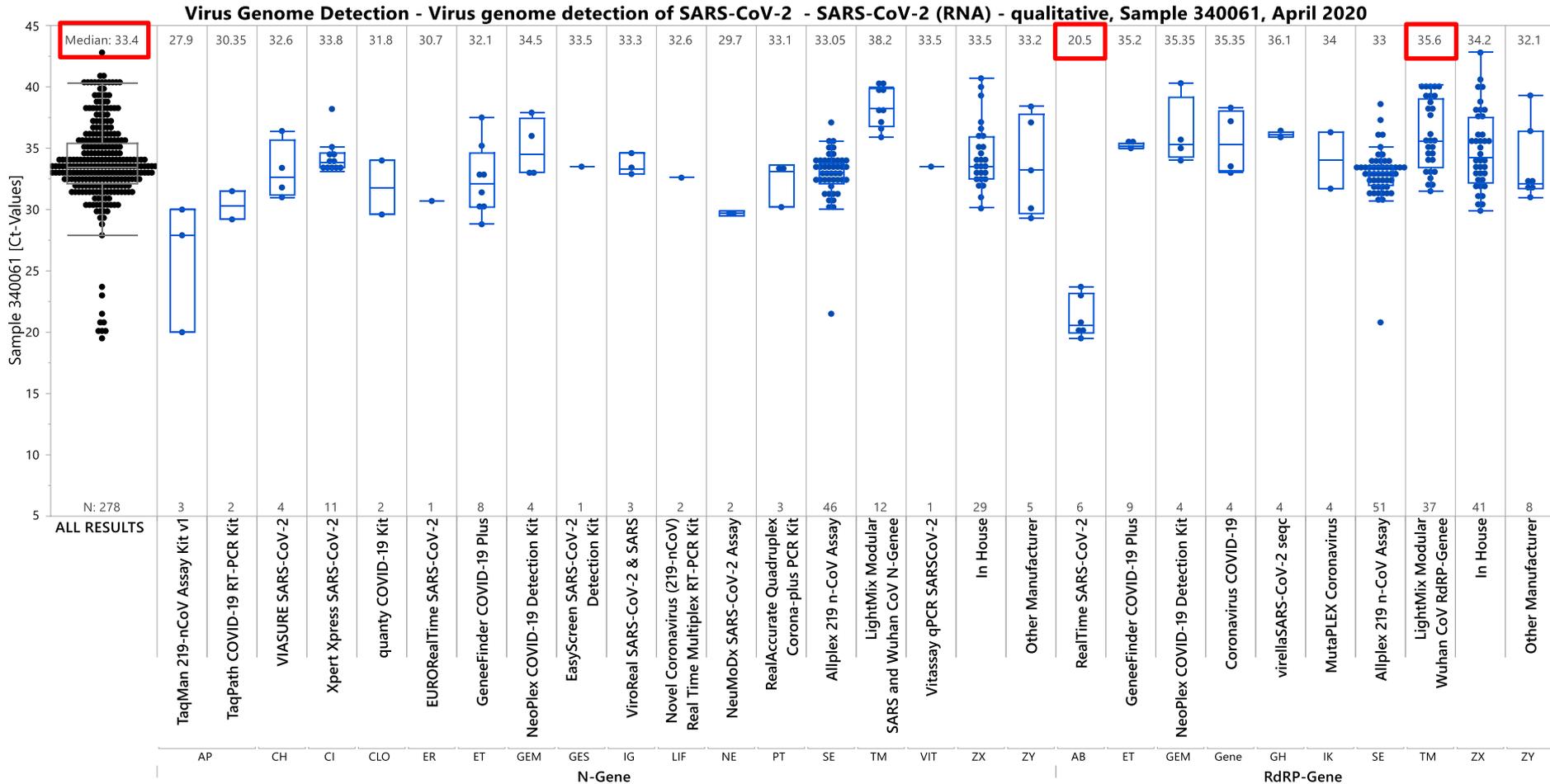
A Sample no.	B Sample properties	D Correct results per reported results differentiated by gene region	D-1 Correct results per reported results differentiated by gene region [reduced by the no. of incorrect result assignments (mix-ups) for samples 340064 and 340065]	E Reported Ct/Cp/Cq/CN-results differentiated by gene region median (min – max)
Sample 340059	SARS-CoV-2 positive* 1 : 1 000 diluted	980/983 (<u>99.7%</u>)		22.8 ←
Sample 340063	SARS-CoV-2 positive* 1 : 10 000 diluted	971/983 (<u>98.8%</u>)		26.0 ←
Sample 340064	SARS-CoV-2 positive* 1 : 100 000 diluted	916/983 (93.2%)	915/925 (<u>98.9%</u>)	29.5 ←
Sample 340061	SARS-CoV-2 positive* 1 : 1 000 000 diluted	914/983 (<u>93.0%</u>)		32.4 ←
Sample 340060	SARS-CoV-2 negative HCoV OC43 1 : 2 500 diluted specificity control	961/983 (<u>97.8%</u>)		-
Sample 340065	SARS-CoV-2 negative HCoV 229E 1 : 2 500 diluted specificity control	908/983 (92.4%)	907/925 (<u>98.1%</u>)	-
Sample 340062	SARS-CoV-2 negative CoV negative MRC-5 cells specificity control	969/983 (<u>98.6%</u>)		-

*strain: BetaCoV/Munich/ChVir984/2020

Extra INSTAND EQA Scheme (340) - April 2020

Virus Genome Detection SARS-CoV-2

sample 340061, 1 : 1 000 000 diluted, Ct values reported for N gene and RdRP gene differentiated according to manufacturer and test name



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Quantitative comparison samples (CS) 1 and 2 plus additional quantitative sample

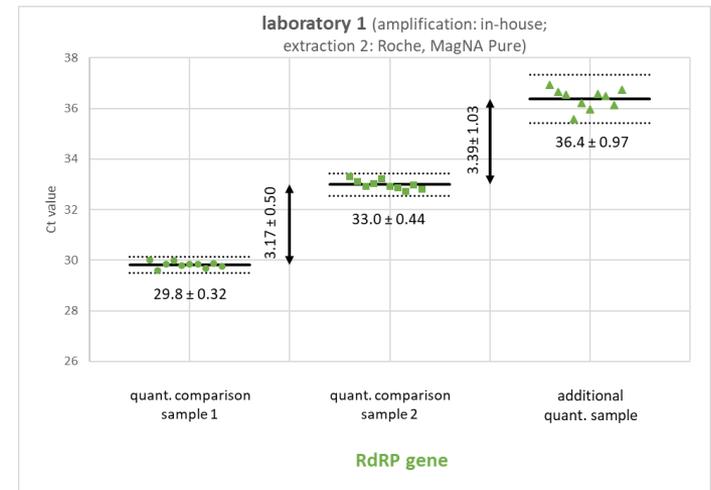
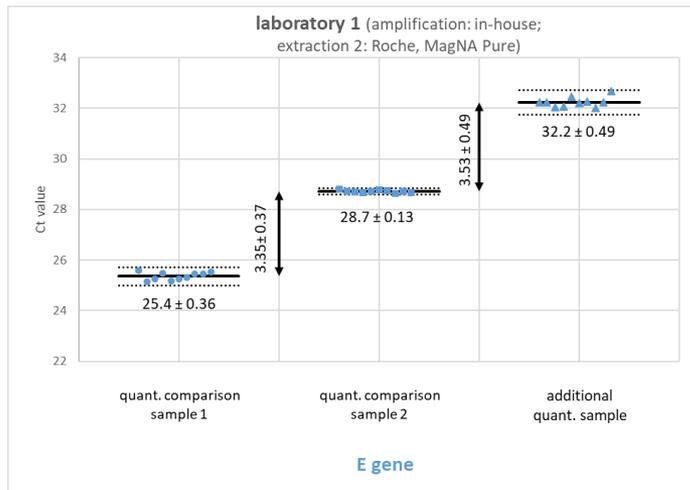
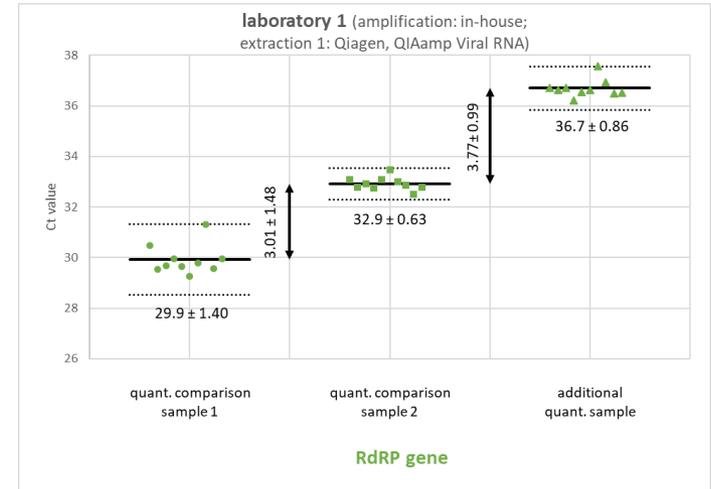
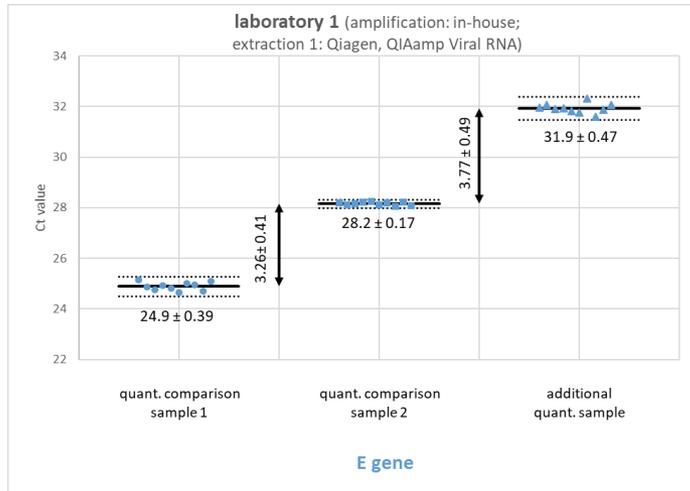
Sample set contains	Virus / matrix	SARS-CoV-2 RNA load*
Quant. comparison sample (CS) 1 Ch07469 (3 vials) shipments: 03.11.2020 + 17.11.2020 + 15.01.2021 + 17.02.2021 + 24.03.2021	SARS-CoV-2 (heat inactivated; 4 hours at 60 °C) Strain: BetaCoV/Munich/ChVir984/2020 lyophilised cell culture lysate, diluted in cell culture medium	approx. 10⁷ copies/ml
Quant. comparison sample (CS) 2 Ch07470 (3 vials) shipments: 03.11.2020 + 17.11.2020 + 15.01.2021 + 17.02.2021 + 24.03.2021		approx. 10⁶ copies/ml
Additional quantitative sample (only for cooperation partners)		approx. 10⁵ copies/ml

*The quantification of CS 1, CS 2 and the additional quantitative sample was carried out with the aid of a synthetic RNA quantification standard and was also derived from measurements using digital PCR (dPCR).

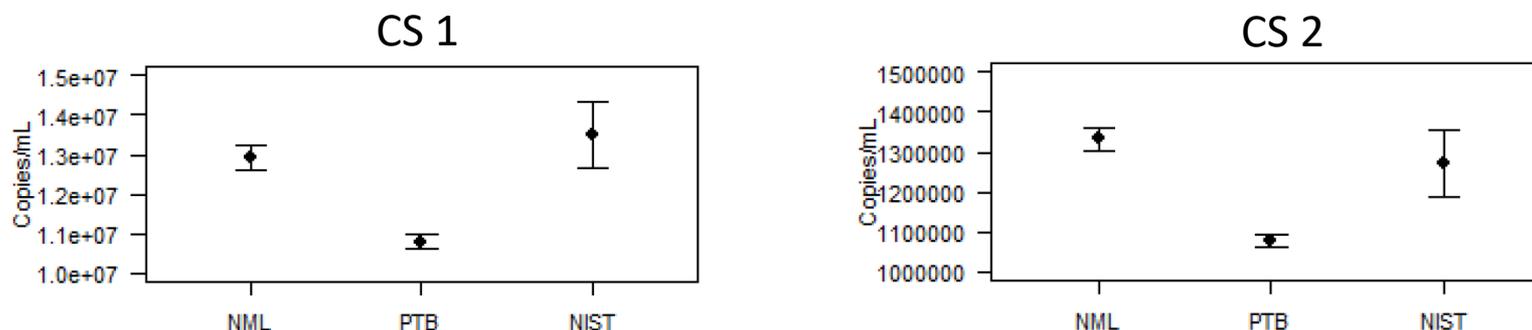
We thank the following National Measurement Institutes for dPCR measurements:

- National Measurement Institute LGC, Teddington, Middlesex (UK)
- Physikalisch-Technische Bundesanstalt, Berlin (DE)
- NIST - National Institute of Standards and Technology, Gaithersburg, MD (USA)

Pre-characterization of quantitative comparison samples (CS) 1 and 2 and additional quantitative sample – laboratory 1 - in house tests

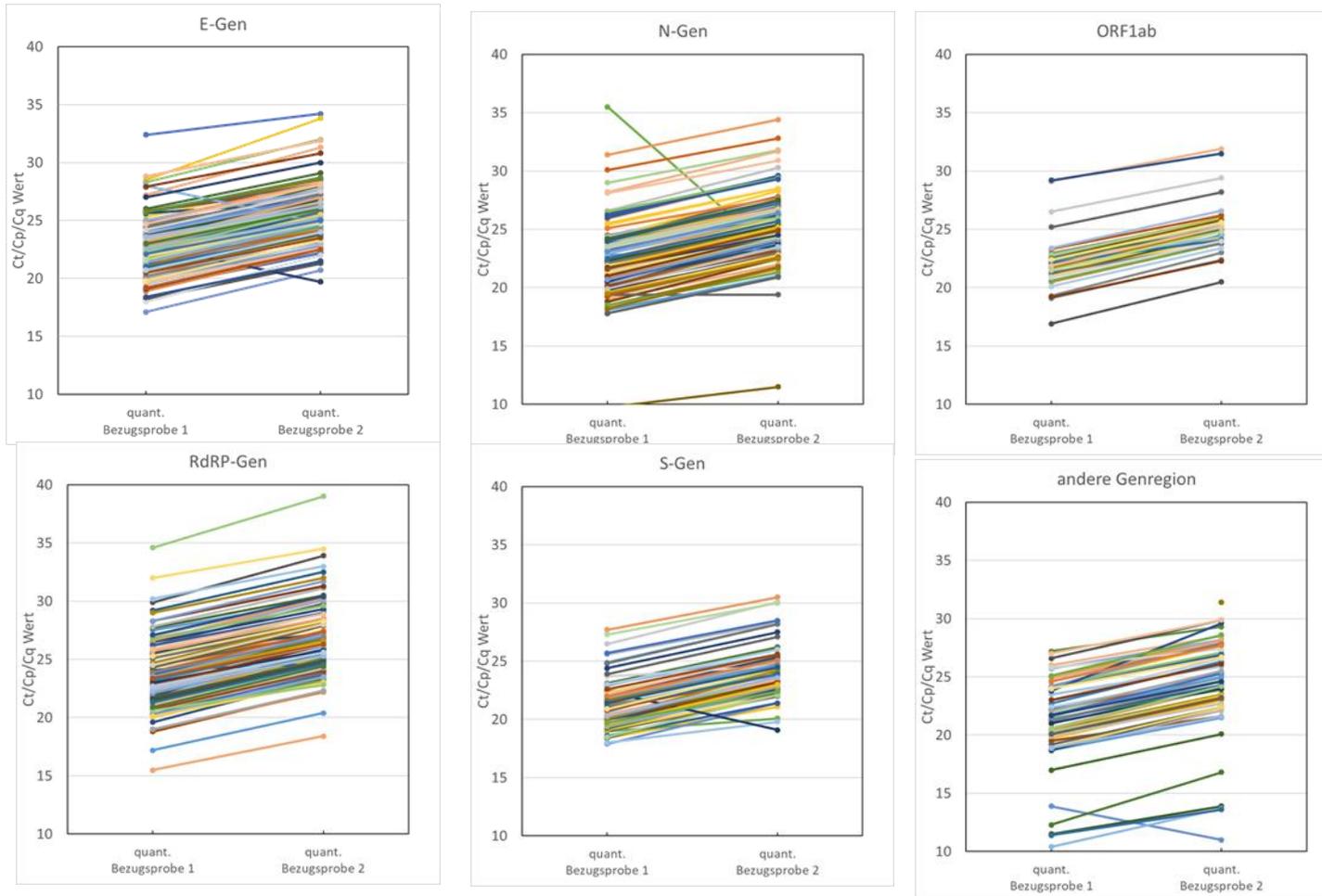


Assignment of SARS-CoV-2 loads to quantitative comparison samples (CS) 1 and 2 by dPCR



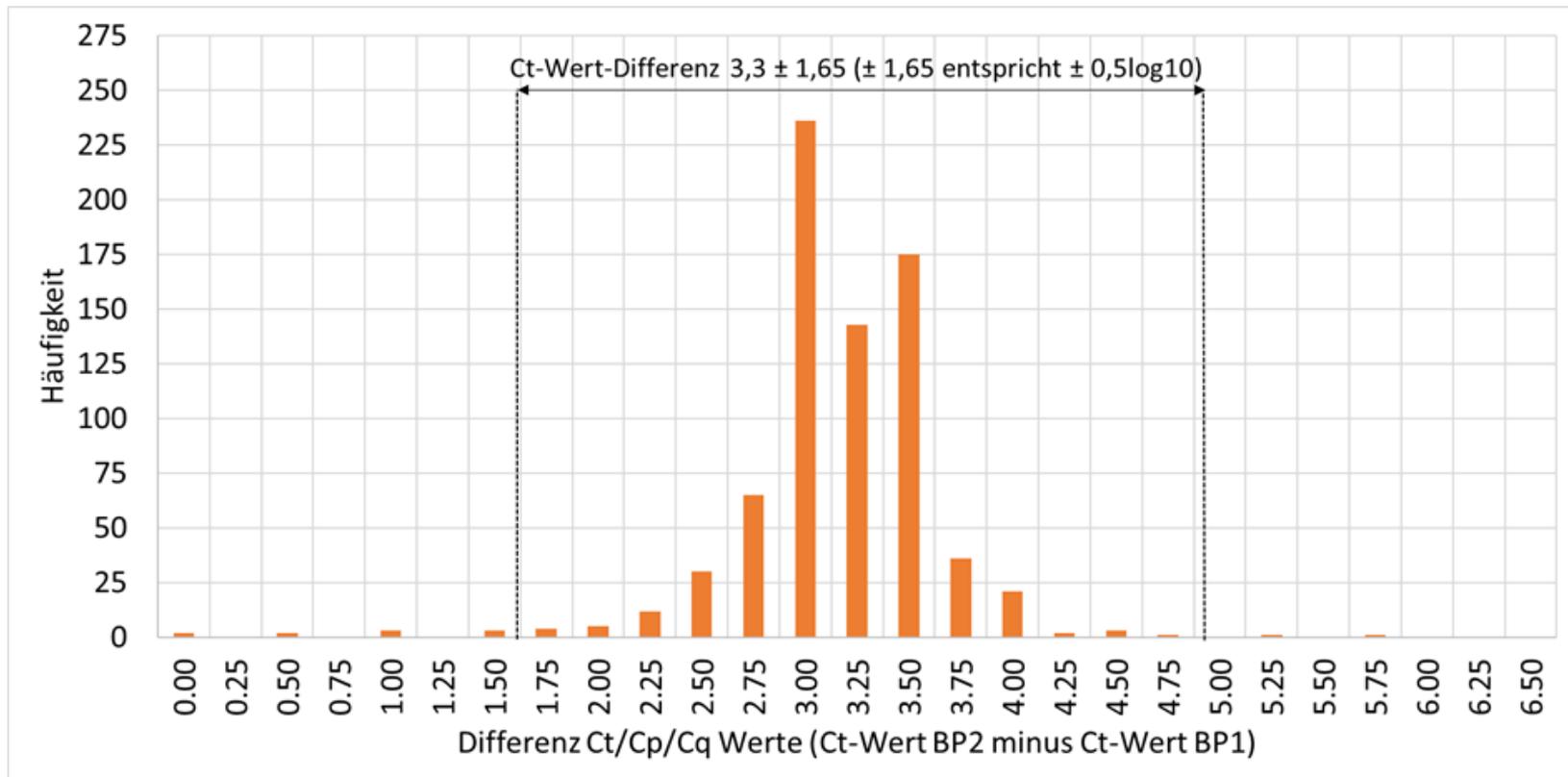
Sample	SARS-CoV-2 load ± expanded uncertainty (95% conf. interval)
CS 1	$(1.24 \pm 0.36) \times 10^7$ copies/ml
CS 2	$(1.23 \pm 0.33) \times 10^6$ copies/ml

Results for quantitative CS 1 and CS 2 of 234 labs (as of 15 Jan 2021) differentiated in regard to gene regions



Results for quantitative CS 1 and CS 2 of 234 labs (as of 15 Jan 2021)

Difference Ct/Cp/Cq values (ct value CS 2 minus ct value CS 1)



Quantitative comparison samples (CS) 1 and 2 - SARS-CoV-2 genome detection

By applying the quantitative comparison samples (CS) 1 and 2,

- each individual lab is able to anchor its obtained ct value
- for a given gene region
- of an individual test with the assigned virus concentration of comparison samples (CS) 1 and 2.

⇒ criteria for assessing samples in routine diagnostics

⇒ **especially for discharge management of patients from isolation**

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Coronavirus Standards Working Group (CSWG)

- **organized by Marc Salit, Ph.D.**

Director, Joint Initiative for Metrology in Biology — <http://jimb.stanford.edu>

SLAC National Accelerator Laboratory

Adjunct Professor, Departments of Bioengineering and Pathology

Stanford University



- project website: <https://jimb.stanford.edu/covid-19-standards>

- **CSWG RNA Harmonization Study**

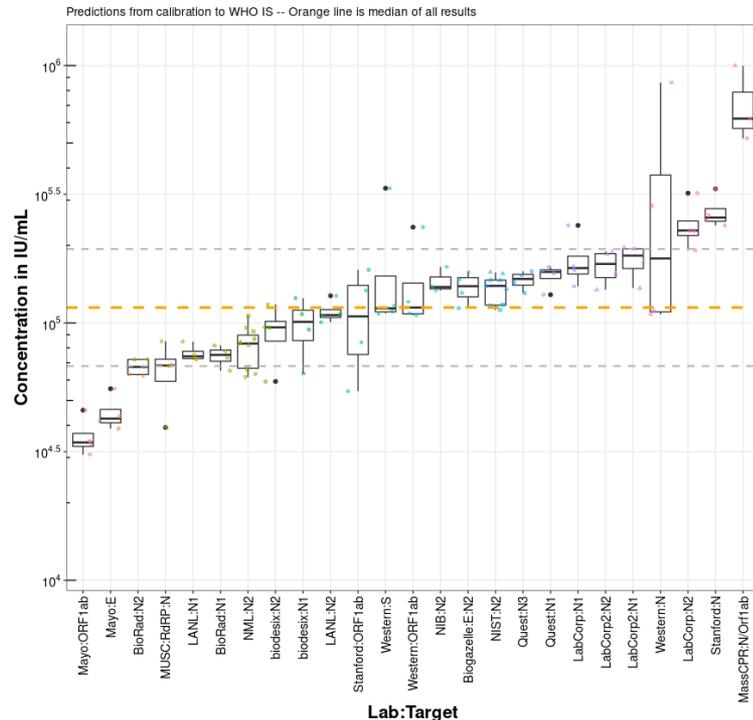
- calibration of SARS-CoV-2 RNA (reference) materials against 1st WHO International Standard for SARS-CoV-2 RNA
- 8 different (reference) materials
incl. INSTAND EQA sample 340069 (June/July 2020)
with 157 000 copies/ml
- calibration performed by 14 laboratories

Coronavirus Standards Working Group (CSWG)

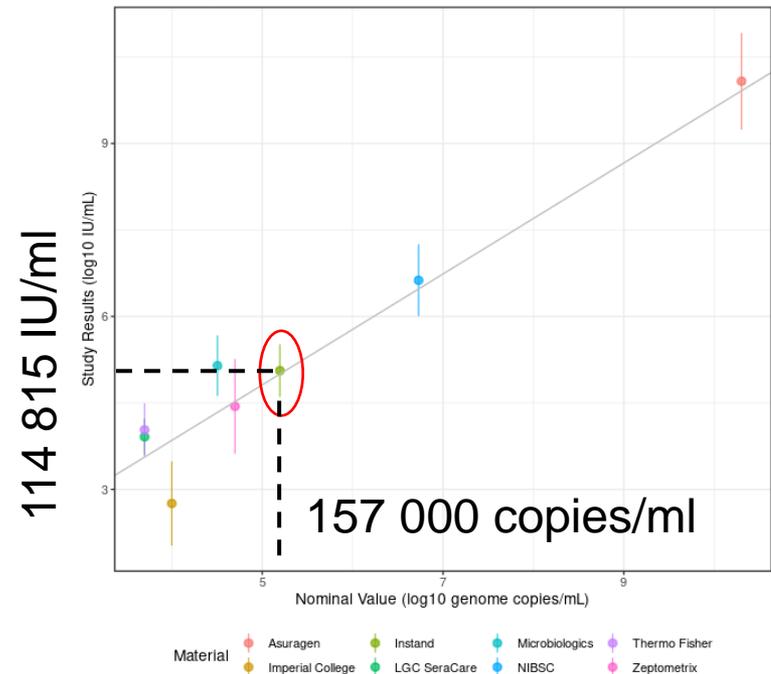
- CSWG RNA Harmonization Study – preliminary results



INSTAND EQA sample 340069:
study results



comparison
nominal values vs. study results
(copies/ml) (IU/ml)



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INSTAND EQA Scheme (416)

Virus Immunology - SARS-CoV-2 (ab)

Cooperation partner

National Consultant Laboratory for Coronaviruses

Institute of Virology, Charité – University Medicine Berlin, Campus Charité Mitte

Christian Drosten

Victor M. Corman

Daniela Niemeyer

Expert Laboratories

Medizinisches Infektiologiezentrum

Berlin - MIB (DE)

Martin Obermeier

Robert Ehret

Medizinisches

Versorgungszentrum Labor 28,

Berlin (DE)

Ralf Ignatius

Heike Kietzmann

Paul-Ehrlich-Institut

Bundesinstitut für Impfstoffe und

biomedizinische Arzneimittel

Prüflabor für IVD, Langen (DE)

Heiner Scheiblauer

Uniklinik Köln,

Institut für Virologie

Nationales Referenzzentrum für

Papillom- und Polyomaviren (DE)

Florian Klein

Rolf Kaiser

Ulrike Wieland

Steffi Silling

Eva Heger

Elena Knops

Universität Würzburg

Institut für Virologie und

Immunbiologie (DE)

Benedikt Weißbrich

Universitätsklinikum Regensburg

Institut für Medizinische

Mikrobiologie und Hygiene

André Gessner

Universitätsklinikum Frankfurt,

Institut für Medizinische Virologie (DE)

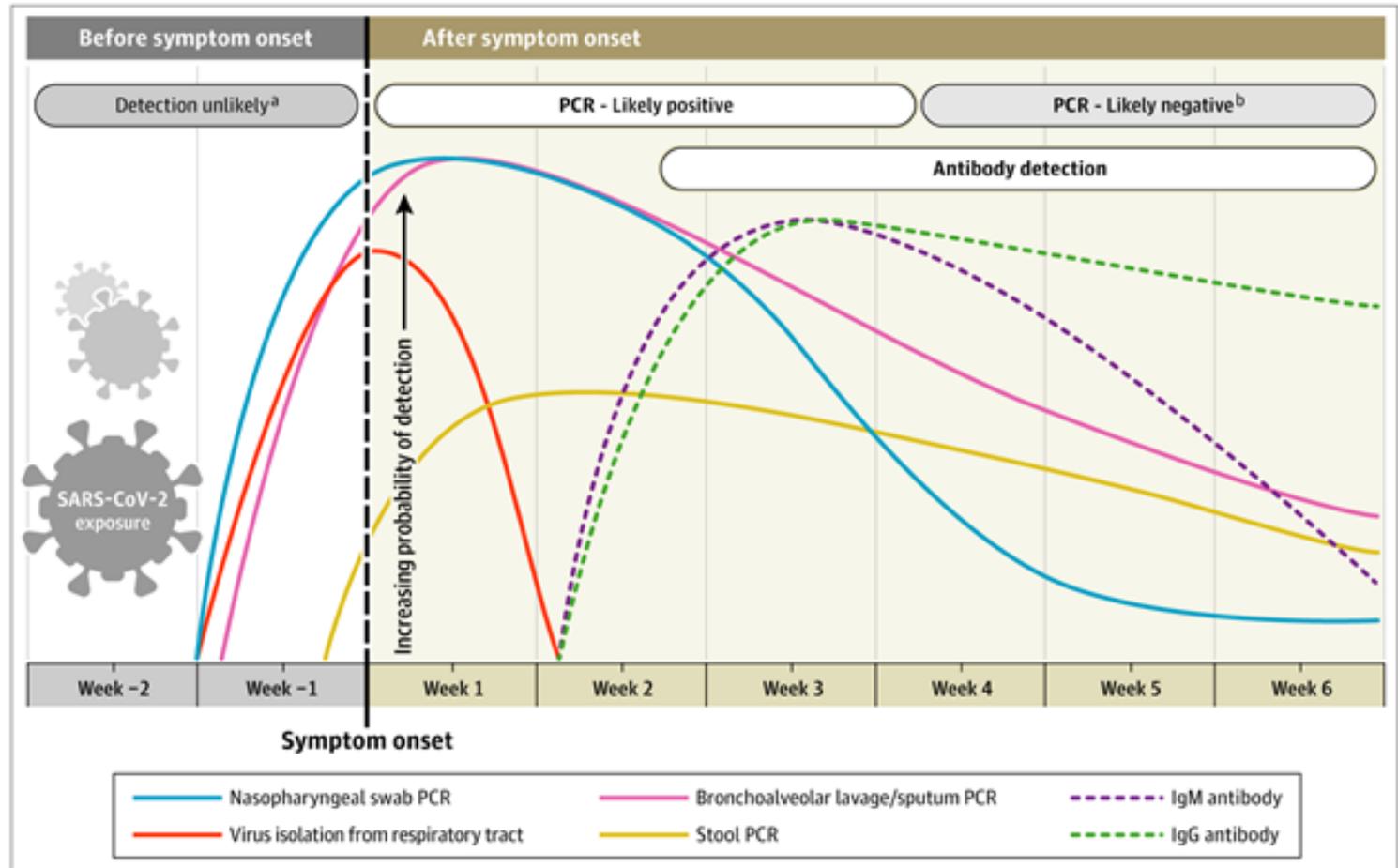
Sandra Ciesek

Holger F. Rabenau

Annemarie Berger

From: Interpreting Diagnostic Tests for SARS-CoV-2

JAMA. Published online May 06, 2020. doi:10.1001/jama.2020.8259



Published online May 06, 2020.

<http://jamanetwork.com/article.aspx?doi=10.1001/jama.2020.8259>

INSTAND EQA Scheme (416)

Virus Immunology - SARS-CoV-2 (ab)

Overview of EQA 7 schemes performed in 2020 and 2021

EQAS term	no of subgroups	52 panel members	no of labs having reported results	no of labs results in BAU/ml	no of countries
May/June 2020	3	12	383	0	27
September 2020	2	8	279	0	23
November 2020	2	8	326	0	21
March 2021	1	4	144	6	11
June 2021	2	8	436	41	28
September 2021	1	4	176	53	13
November 2021	2	8	(429)		30
total:	13	52	707	84	37

for each of the 52 panel members:

native patient serum or patient plasma (not re-calcified) from one individual donor only

- serum from patients after SARS-CoV-2 infection (PCR confirmed) – paired sera
- serum/plasma from patients after HCoV infection (PCR confirmed)
- serum from healthy blood donors after COVID-19 vaccination
- serum from healthy blood donors from 2015 and earlier



INSTAND EQA Scheme (416) Anti-SARS-CoV-2

Results for Specificity Samples

Blood Donations 2011 - 2015

EQA scheme	Sample	Sample source	Success rate for the detection of anti-SARS-CoV-2			
			Ab total	IgG	IgA	IgM
May/June 20	416002	healthy blood donor from 2015	negative 98.2% (55/56)	negative 98.2% (168/171)	negative 100% (62/62)	negative 100% (35/35)
May/June 20	416008	healthy blood donor from 2015	negative 100% (45/45)	negative 99.4% (155/156)	negative 98.0% (48/49)	negative 100% (51/51)
May/June 20	416009	healthy blood donor from 2015	negative 100% (46/46)	negative 97.9% (143/146)	negative 100% (46/46)	negative 100% (43/43)
Sep 20	416015	healthy blood donor from 2015	negative 98.5% (64/65)	negative 98.9% (174/176)	negative 98.5% (67/68)	negative 100% (27/27)
Sep 20	416017	healthy blood donor from 2015	negative 95.2% (40/42)	negative 97.0% (130/134)	negative 100% (25/25)	negative 93.1% (67/72)
Nov 20	416026	healthy blood donor from 2011	negative 98.4% (62/63)	negative 99.0% (191/193)	negative 98.7% (74/75)	negative 100% (39/39)
Nov 20	416032	healthy blood donor from 2013	negative 100% (59/59)	negative 97.3% (142/146)	negative 92.5% (37/40)	negative 100% (64/64)
March 21	416035	healthy blood donor from 2014	negative 98.6% (73/74)	negative 98.0% (150/153)	negative 97.6% (40/41)	negative 100% (57/57)
Jun 21	416040	healthy blood donor from 2014	negative 98.2% (107/109)	negative 98.7% (236/239)	negative 100% (76/76)	not evaluated (58/60 reported neg.)
Sep 21	No specificity samples deployed					

9 sera of German healthy blood donors (2011 – 2015):

Specificity (negative for anti-SARS-CoV-2) shown in **141 tests of 62 manufacturers**

INSTAND EQA Scheme (416) Anti-SARS-CoV-2

Results for Specificity Samples

Anti-Human CoVs - 229E, OC43 and HKU1

EQA scheme	Sample	Sample source	Time after onset of disease	Success rate for the detection of anti-SARS-CoV-2			
				Ab total	IgG	IgA	IgM
May/June 20	416004	patient 3 after HCoV 229E infection	3 months	negative 100% (56/56)	negative 99.4% (170/171)	negative 95.2% (59/62)	negative 97.1% (34/35)
May/June 20	416006	patient 5 after HCoV OC43 and HCoV HKU1, respectively	2 years and 5 years, respectively	negative 100% (45/45)	negative 99.4% (155/156)	negative 83.7% (41/49)	negative 90.2% (46/51)
May/June 20	416012	patient 9 after HCoV HKU1 infection	3 months	negative 97.8% (45/46)	negative 97.9% (143/146)	negative 89.1% (41/46)	negative 97.7% (42/43)

3 sera of donors previously infected with HCoVs:

Specificity (negative for anti-SARS-CoV-2) shown in **48 tests of 27 manufacturers**

INSTAND EQA Scheme (416) Anti-SARS-CoV-2 – Sep 2021

individual immune response – paired sera of patient **L**

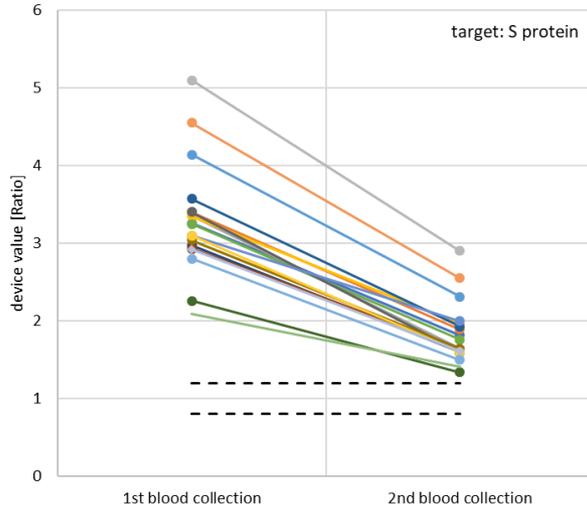
EQA scheme	Sub-group (SG)	Sample	Sample source all infections PCR confirmed	Time after onset of disease	Success rate for the detection of anti-SARS-CoV-2					
					Ab total			IgG		
					Spike+NCP	Spike	NCP	Spike+NCP	Spike	NCP
Sep 20	-	416045	<u>patient L</u> after SARS-CoV-2 infection (1st blood collection)	<u>70 days</u>	positive 100% (1/1)	positive 96.2% (51/53)	positive 100% (36/36)	positive 95.5% (21/22)	positive 100% (121/121)	positive 100% (24/24)
Sep 20	-	416046	<u>patient L</u> after SARS-CoV-2 infection (2nd blood collection)	<u>289 days</u>	positive 100% (1/1)	positive 94.3% (50/53)	positive 100% (36/36)	positive 81.8% (18/22)	positive 93.4% (113/121)	not evaluated reported positive 12.5% (3/24)

INSTAND EQA Scheme (416) Anti-SARS-CoV-2 – Sep 2021

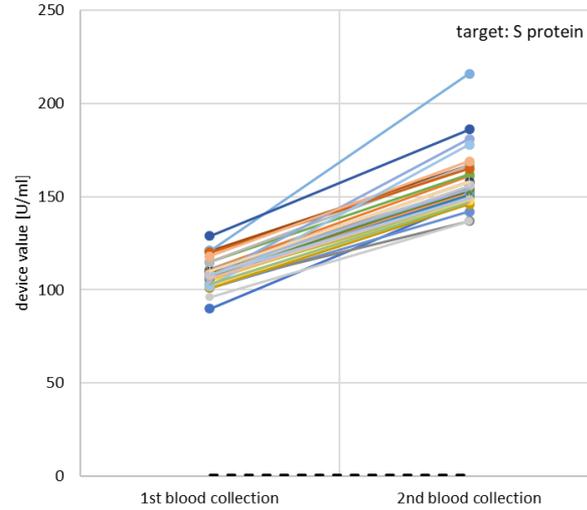
individual immune response – paired sera of patient L

days after onset of disease: 1st = 70 d, 2nd = 289 d

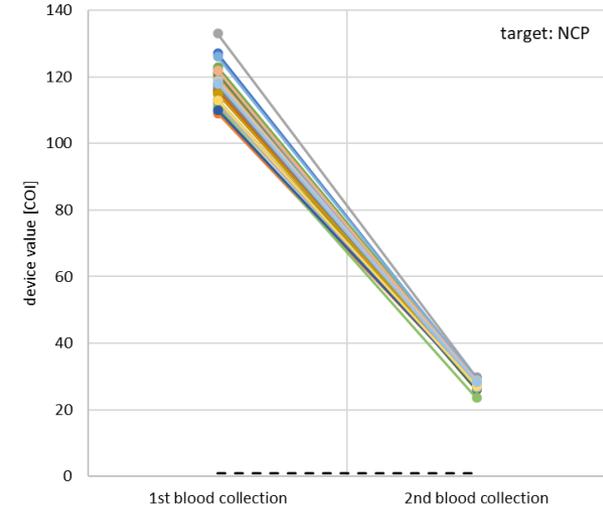
Euroimmun Anti-SARS-CoV-2-ELISA IgG



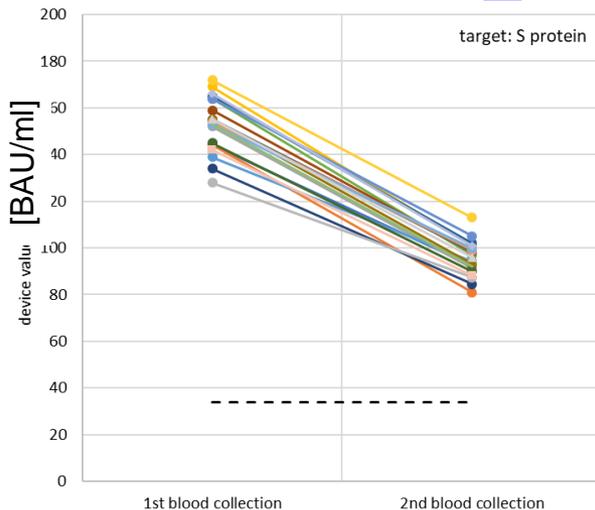
Roche Elecsys Anti-SARS-CoV-2 S Total



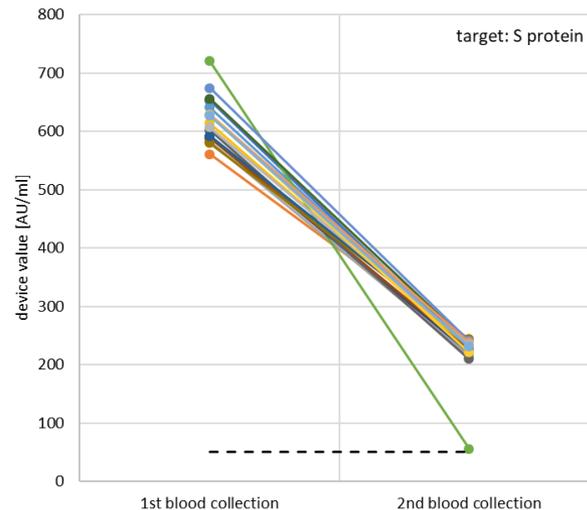
Roche Elecsys Anti-SARS-CoV-2 Total



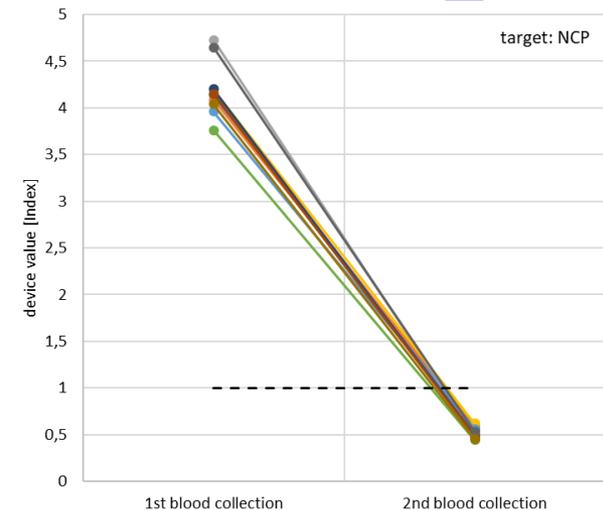
DiaSorin LIAISON SARS-CoV-2 TrimericS IgG



Abbott ARCHITECT SARS-CoV-2 IgG II Quant



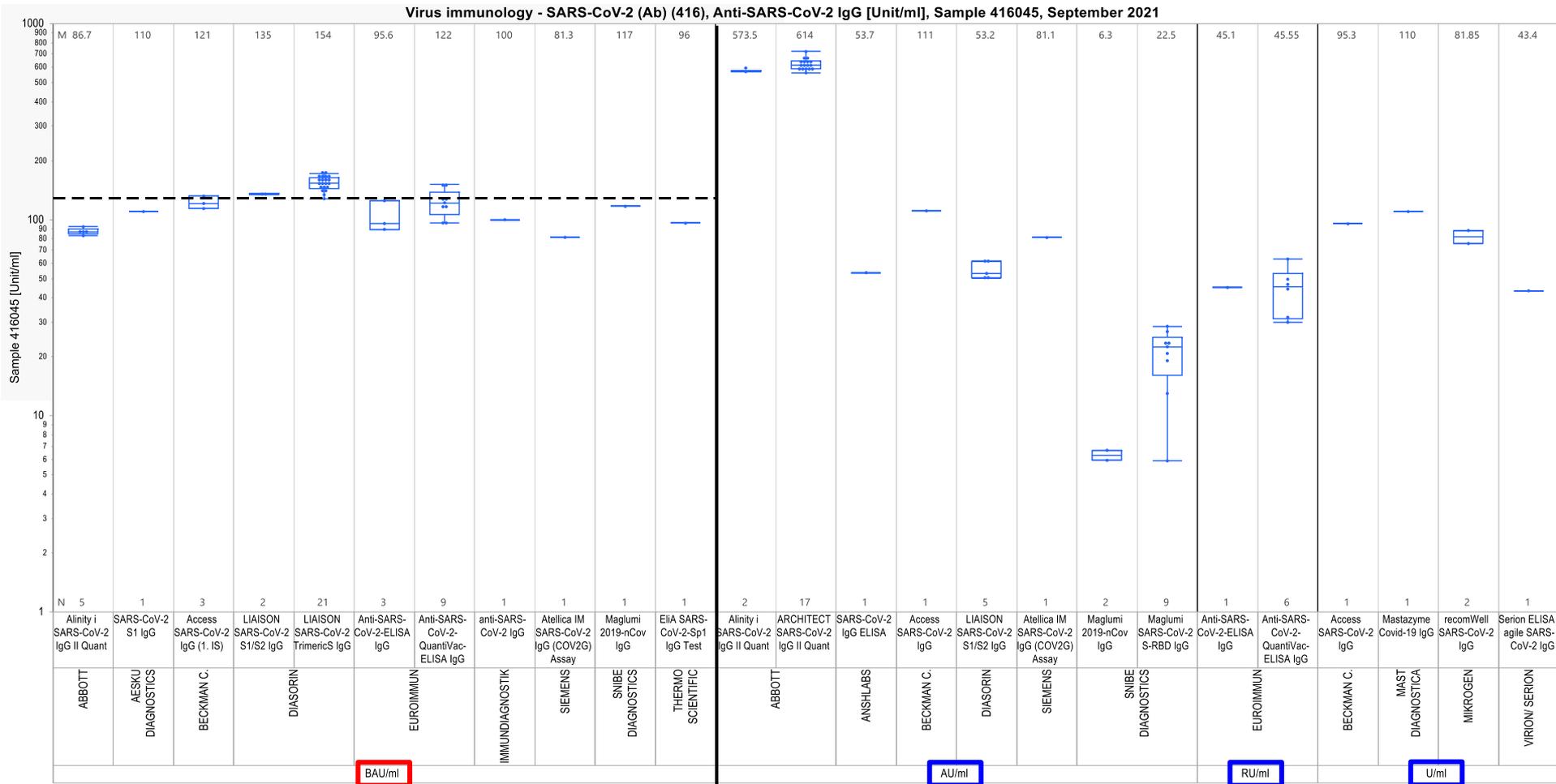
Abbott ARCHITECT SARS-CoV-2 IgG



INSTAND EQA Scheme (416) Anti-SARS-CoV-2 – Sep 2021

individual immune response – paired sera of patient L

spl. 416045, patient L, blood collected 73 days after onset of disease



M = Median
N = Number

-- robust average (statements in BAU/ml): 129 BAU/ml

Summary

- INSTAND External Quality Assessment (EQA) Schemes
- (MK) EQAS for SARS-CoV-2 genome detection (starting April 2020)
 - strong variation of ct-values
 - how to interpret ct-values as positive for SARS-CoV-2=> standardization of SARS-CoV-2 genome detection needed
- (MK) Use of quantitative comparison samples (CS) for anchoring ct-values
 - for individual labs
 - for defined tests
 - for each individual gene region
- (MK) Results of RNA Harmonization Study (CSWG)
 - good correlation between copies/ml of investigated reference materials and IU/ml of WHO IS (NIBSC 20/146)
- (HZ) EQAS for SARS-CoV-2 antibody detection (starting May 2020)
 - good specificity
 - individual immune responses in regard to target antigens (S/NCP)
 - quantitative results in BAU/ml (WHO IS, NIBSC 20/136) of different tests in good agreement

Thank you very much!

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INSTAND EQA schemes in virus diagnostics

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